REMARKS

I. Interview Summary

Applicants wish to thank Examiners Barham and Woodward for graciously consenting to an interview with Applicants' representatives on January 28, 2008. Applicants would also like to thank the Examiners for their indication that the rejections under 35 U.S.C. § 112 could be overcome by amending claim 1 to recite the limitations of pending claims 7 and 9, and that a Declaration under 37 C.F.R § 1.131 in traversal of the rejection under 35 U.S.C. § 103 would be considered after final.

II. Amendments to the Specification and Claims

The specification was amended by Applicants on October 22, 2007 ("Applicants' prior Reply") by the insertion of a paragraph between original paragraphs **[0031]** and **[0032]**. In the present Amendment and Request for Reconsideration under 37 C.F.R. § 1.116 ("Applicants' present Reply"), Applicants have deleted without prejudice or disclaimer the previously inserted paragraph in its entirety in order to expedite allowance of the claims. Applicants reserve the right to pursue the deleted subject matter in the future.

Claim 1 has been amended to recite the water insoluble polymers of claim 7 (as previously presented in Applicants' prior Reply), and the plasticizers of original claim 9. Water insoluble polymers incorporated by reference in Applicants' prior Reply have been deleted from claim 1 without prejudice or disclaimer in order to expedite allowance of the claims. Applicants reserve the right to pursue the deleted subject matter in the future.

Claims 5, 7-9, 28, and 37-38 have been canceled without prejudice to their further prosecution.

Claims 11 and 27 have been amended to change their dependency from deleted claim 7 to claim 1. Claim 26 has been amended to change its dependency from deleted claim 9 to claim 1. Claims 29 and 30 have been amended to change their dependency from deleted claim 28 to claim 1. These amendments are supported by claims 7 and 9 as originally filed, and the specification at paragraph **[0034]**.

No new matter is believed to have been added by these amendments. Claims 1-4, 6, 10, 11, 24-27, 29-36, and 39 are active.

III. Objections

The Examiner alleges that the subject matter of U.S. 5,120,548 and WO 98/18610 added to the specification and claims by Applicants' prior Reply is "new matter". As discussed in Section II above, the subject matter incorporated by reference and previously inserted into the specification and claims in Applicants' prior Reply has been deleted in its entirety. Thus, the "new matter" objection to the specification and claims has been rendered moot by the present amendments. Accordingly, Applicants respectfully request that the objection be withdrawn.

Although Applicants have now deleted the subject matter incorporated by reference and previously inserted into the specification and claims, Applicants reserve the right to pursue the deleted subject matter in the future. Applicants respectfully submit that the amendments to the claims and specification submitted in Applicants' prior Reply recited subject matter that was properly incorporated by reference, and thus the amended specification did not contain "new matter".

IV. Rejections under 35 U.S.C. §112, First Paragraph

A. New Matter

The Examiner has rejected claims 1-11 and 24-40 as "incorporat[ing] new matter". As indicated in Section II above, the subject matter incorporated by reference and previously inserted into the claims in Applicants' prior Reply has been deleted in its entirety. Thus, the "new matter" rejection of the claims has been rendered moot by the present amendments. Accordingly, Applicants respectfully request that the rejection be withdrawn.

B. Written Description

The Examiner has rejected claims 1-11 and 24-40 because the "claims contain no actual structure". Applicants respectfully request reconsideration.

Amended claim 1 recites "an active-containing core particle" which comprises "cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof" and "an extended release coating comprising a water insoluble polymer membrane surrounding said core". The "water insoluble polymer membrane" itself comprises "a water insoluble polymer selected from the group consisting of ethers of cellulose, esters of cellulose, cellulose acetate, ethyl cellulose, polyvinyl acetate, neutral copolymers based on ethylacrylate and methylmethacrylate, copolymers of acrylic and methacrylic acid esters with quaternary ammonium groups, pH-insensitive ammonio methacrylic acid copolymers, and mixtures thereof" in combination with "a plasticizer selected from the group consisting of triacetin, tributyl citrate, tri-ethyl citrate, acetyl tri-n-butyl citrate, diethyl phthalate, dibutyl sebacate, polyethylene glycol, polypropylene glycol, castor oil, acetylated mono- and di-glycerides and mixtures thereof". Thus, amended claim 1 unambiguously recites significant structure expressly supported by the specification and claims as originally filed.

Furthermore, functional limitations are not *per se* improper, and must be considered like any other claim limitations. (*See* MPEP 2173.05(g)[1]). Applicants note that the specification provides a number of examples of compositions according to the claimed invention providing, e.g., the claimed dissolution properties (*see* Examples 2 and 3, Figures 3-6) and claimed pharmacokinetic properties (*see* Examples 4 and 5, Table 1). Thus, the present specification clearly supports the structural and functional limitations of the claimed invention.

V. Rejections Under 35 U.S.C. §103

[1] "Functional language does not, in and of itself, render a claim improper. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used."

The Examiner has rejected the claims over the combination of U.S. 2004/0197407 ("Subramanian") and either U.S. 2003/0215496 ("Patel") or U.S. 2003/0099711 ("Meadows"). Subramanian was filed February 11, 2004 (claiming priority to U.S. 60/446425, filed February 11, 2003) and published October 7, 2004. The present application was filed November 14, 2003. Accordingly, Subramanian is only available as a reference under 35 U.S.C. §102(e).

Applicants have submitted herewith a Declaration under 37 C.F.R. §131 by inventor G. Venkatesh ("Declaration") documenting the preparation by Applicants of specific multi-particulate dosage forms according to the claimed invention, prior to February 11, 2003, which are described in Examples 3-5 and Figures 4 and 6 of the specification.

Example 3 of the present specification describes the preparation of a composition according to the claimed invention, comprising cyclobenzaprine hydrochloride coated onto sugar spheres in a 50/50 acetone/purified water solution. The cyclobenzaprine hydrochloride coated "beads" are seal coated with Opadry® (hydroxypropylmethylcellulose), then coated with an extended release coating comprising ethyl cellulose (i.e., a water-insoluble polymer) and diethyl phthalate (i.e., a plasticizer) in a solution of 98/02 acetone/purified water. Batches coated to various coating weights, including 10% were prepared, and dissolution profiles are presented in Figure 4. One of the compositions disclosed in Figure 4 is designated "10% ER Coating Wt., Batch 805AAA105".

Exhibit A of the Declaration, dated prior to February 11, 2003, documents the preparation of "Cyclobenzaprine HCl, Drug Layered Beads" designated "Batch Number: **837AG034**", and comprising "Cyclobenzaprine HCl" dissolved in "Acetone, NF 50/50 Ratio" and "USP Purified Water, 50/50 Ratio" coated onto "Sugar Spheres", and subsequently coated with "Opadry Clear".

Exhibit B of the Declaration, dated prior to February 11, 2003, documents the extended release coating composition for "Lot # **805-AAA-105**". The extended release coating composition comprises "Ethylcellulose 10P Premium (10 cps)" and "Diethyl Phthalate" dissolved in "Acetone, NF (98 parts)" and "Purified Water, USP (2 parts)", coated onto "Cyclobenzaprine HCl, Drug Layered Beads" identified as "**837-AG-034**" (i.e., the cyclobenzaprine layered beads of Exhibit A).

Exhibit C of the Declaration, dated prior to February 11, 2003, documents dissolution data for sample "**805-AAA-105-10**" (i.e., the extended release coated beads of Exhibit B) which corresponds to the data graphically represented for "Batch 805AAA105" in Figure 4. The dissolution data for "Batch 805AAA105" in Exhibit C and Figure 4 meet the claimed "drug release profile" limitations.

Thus, Exhibits A-C document the preparation and evaluation of a composition described in Example 3 of the present specification.

Example 4 of the specification describes the preparation of scaled up batches of cyclobenzaprine hydrochloride dosage forms of the claimed invention, prepared by "layering" cyclobenzaprine hydrochloride onto "sugar spheres", followed by "seal coating" and "ER [c]oating". The drug release profiles of the "three registration stability batches" and one "clinical" batch are presented in Figure 6 of the present specification. The pharmacokinetic data for the "clinical" batch is presented in Example 5 of the present specification.

Exhibit D of the Declaration, dated prior to February 11, 2003, documents the manufacture of "Cyclobenzaprine HCl MR Capsules, 30 mg", Lot # "**PF306EA001**" containing "Cyclobenzaprine HCl Extended Release Beads", Item code "**PE271**".

Exhibit E of the Declaration, dated prior to February 11, 2003, documents the coating of "Cyclobenzaprine HCl Intermediate Beads" with "Ethylcellulose" and "Diethyl Phthalate" dissolved in "Acetone" and "Purified Water". The coated beads are designated lot # "**PE271EA001**" (i.e., the cyclobenzaprine layered beads of Exhibit D).

Exhibit F of the Declaration, dated prior to February 11, 2003, documents dissolution data for "Cyclobenzaprine 30 mg MR Capsules Lot # PF306EA001" (i.e., the extended release coated beads of Exhibit E) which corresponds to the data graphically represented for "PF306EA001" in Figure 6. The dissolution data for "PF306EA001" in Exhibit F and Figure 6 meet the claimed "drug release profile" limitations.

Applicants also note that Lot # **PF306EA001** is the "clinical" batch described in Example 5 and Table 1 of the present specification.

Thus, Exhibits D-F document the preparation and evaluation of a composition described in Examples 4 and 5 of the present specification.

As indicated above, Exhibits A-F document that Applicants prepared the compositions disclosed in Examples 3-5, Table 1, and Figures 4 and 6 of the present specification, and at least one of these compositions meets all of the limitations of the pending claims. Thus, Applicants invented the claimed invention prior to February 11, 2003 (*i.e.*, the priority date of Subramanian). Accordingly, Subramanian is not properly available as a reference.

As tacitly admitted by the Examiner, neither Patel nor Meadows, individually, anticipate or suggest the claimed invention, since the Examiner's arguments depend on their combination with Subramanian to allegedly provide the claimed invention. Accordingly, Applicants respectfully request that the rejection be withdrawn.

VI. Conclusion

For the reasons stated above, Applicants respectfully submit that the claims are now in condition for allowance, early notice of which is respectfully requested. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

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Respectfully submitted,
COOLEY GODWARD KRONISH LLP

By: _____
Michael S. Tuscan
Reg. No. 43,210

COOLEY GODWARD KRONISH LLP
CUSTOMER NUMBER 58249
ATTN: Patent Group
777 6th Street, NW, Suite 1100
Washington, DC 20001
Tel: (202) 842-7802
Fax: (202) 842-7899